II. REMARKS

Upon entry of the present amendment, claims 1 to 4, 9 to 12, 15, 19 to 22, 26 to 41 will be pending. A marked version showing the amendments to the claims is attached hereto as Exhibit A. For the Examiner's convenience, Exhibit B lists all pending claims, upon entry of the present amendment, organized such that dependent claims more closely follow the independent claims from which they depend.

A. Regarding the Amendments

Claims 5 to 8, 13, 14, 16 to 18, and 23 to 25 have been cancelled herein without disclaimer, and without prejudice to Applicants' pursuing prosecution of subject matter encompassed within one or more of the claims in an application claiming the benefit of priority of the subject application.

Claim 1 has been amended to recite specific structural and functional features of a promyostatin signal peptide domain encoded by the claimed polynucleotide. The amendment is supported, for example, at page 17, lines 1-13, and page 21, lines 12-16. Claim 3 has been amended to incorporate the language of originally filed claims 5 and 7, which have been cancelled. Claim 4 has been amended to include language of previously pending claims 6 and 8, which have been cancelled. Claim 15 has been amended to depend from claim 1.

Claim 19 has been amended to more clearly recite structural and functional features of a promyostatin myostatin domain encoded by the claimed polynucleotide. The amendment is supported, for example, at page 23, lines 4-10, and page 21, lines 12-16. Claims 20 and 21 have been amended such that the language corresponds to that used in claim 19, from which claims 20 and 21 depend. Claim 21 also has been amended to incorporate that language of previously pending claims 23 and 25, which have been cancelled. Claim 22 has been amended to incorporate that language of previously pending claims 24 and 26; claim 24 has been cancelled, and claim 26 has been amended to an independent form. Claim 26 also has been amended to clarify that it is directed

to a promyostatin myostatin domain. The amendment is supported by claim 26 as originally filed and, for example, at page 32, lines 24-29.

New claims 30 to 41 have been added. New claims 30 and 31, which depend from claim 19, are supported, for example, at page 3, line 26, to page 4, line 3; and page 32, lines 24-29. New claim 32, which also depends from claim 19, is supported, for example, by originally filed claim 11.

New claim 33 is supported, for example, at page 22, line 30, to page 23, line 10, and page 21, lines 12-16. New claims 34 and 35 are supported, for example, by original claim 2 and claims 3, 5 and 7, respectively. New claim 36 is supported, for example, at page 3, line 26, to page 4, line 3. New claim 37 is supported, for example, at page 23, lines 4-10. New claim 38 is supported, for example, at page 22, line 30, to page 23, line 4. New claims 39 and 40 are supported, for example, by originally filed claims 9 and 11. New claim 41 is supported, for example, by originally filed claim 15.

As indicated above, the amendments to the claims and the newly added claims are supported by the specification, including the claims as originally filed, and, therefore, do not add new matter. It is submitted that the amended and new claims do not require a new search (except with respect to the non-elected species, see Section B, below) and do not raise new issues for consideration because the subject matter of the amended and new claims encompasses that which has been examined and is of issue in this case. It is further submitted that the amendments and new claims place the application in condition for allowance, or in better condition for appeal by reducing the issues under consideration. In addition, it is noted that the number of new claims is the same as the number of claims previously under consideration. Accordingly, it is respectfully requested that the Examiner enter the amendments and new claims.

B. Regarding the Species Election

In the Communication regarding a Species Election mailed July 16, 2001 (Paper No. 7), it was stated that, upon allowance of a generic claim, additional species (in addition to elected species SEQ ID NOS:3 and 4) that are written in a dependent form or otherwise include the limitation of the allowed generic claim would be entitled to consideration. For the reasons set forth below, it is submitted that generic claims are allowable and, therefore, is respectfully requested that the additional species as recited in the claims be considered.

C. Double Patenting Rejection

Claims 1 to 4, 9 to 22 and 27 to 29 are rejected under the judicially established doctrine of obviousness-type double patenting over claims 2 to 11 of U.S. Patent No. 5,827,733.

Applicants have submitted herewith a Terminal Disclaimer, disclaiming any term of a patent issuing from the subject application that may extend beyond the term of U.S. Patent No. 5,827,733. Accordingly, it is respectfully requested that this rejection be removed.

The rejection of claims 1 to 4, 9 to 22 and 27 to 29 are rejected under the judicially established doctrine of obviousness-type double patenting over claims 21 to 23 of copending application U.S. Serial No. 09/628,112 is respectfully traversed.

Pursuant to a restriction requirement, claims 21 to 23 of U.S. Serial No. 09/628,112 were cancelled. As such, it is respectfully requested that this rejection be removed.

E. Rejections under 35 U.S.C. § 112

The objection to the specification and corresponding rejection of claims 1 to 4, 9 to 22 and 27 to 29 under 35 U.S.C. § 112, first paragraph, as allegedly lacking an adequate written description are respectfully traversed.

It is maintained in the Office Action that the specification does not adequately describe "functional fragments" of a promyostatin polypeptide that can affect all steps in myostatin signal

transduction. The claims have been amended to more clearly specify structural and functional features of peptides of promyostatin encoded by a claimed polynucleotide. Specifically, the claims indicate that promyostatin peptides comprising the specified amino acid residues have specific functions, including signal peptide activity (claim 1), muscle growth inhibitory activity (claims 19 and 26), and myostatin binding activity (claim 33). It is submitted that the specification provides numerous examples of peptides of promyostatin polypeptides having the recited structural and functional features (see, for example, page 4, line 26, to page 5, line 22). As such, it is submitted that the skilled artisan, viewing the specification, would have been apprised of the subject matter of the invention and, therefore, it is respectfully requested that the rejection of claims as allegedly lacking an adequate written description in the specification be removed.

The objection to the specification and corresponding rejection of claims 1 to 4, 9 to 22 and 27 to 29 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement are respectfully traversed.

It is maintained in the Office Action that the specification does not reasonably enable the skilled artisan to make and use polynucleotides encoding all peptides of promyostatin encompassed within the claims because the "functions" of such peptides are broadly defined. As discussed above, the claims have been amended to more clearly recite structural and functional features of the promyostatin peptides encompassed within the claimed polynucleotides, and the specification provides numerous examples of such peptides. As such, it is submitted that the skilled artisan, viewing the specification, would have known how to make and use the claimed polynucleotides and, therefore, is respectfully requested that the rejection of the claims as allegedly lacking enablement by the specification be removed.

The rejection of claims 1 to 4, 9 to 22 and 27 to 29 under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter of the invention is respectfully traversed.

It is maintained in the Office Action that the terms "proteolytic fragment" and "functional peptide portion" are not clear and definite. The claims as amended no longer recite these terms. As such, it is respectfully requested that the rejection of the claims under 35 U.S.C. § 112, second paragraph, be removed.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, the Commissioner is authorized to charge any fee (or credit any overpayment) to Deposit Acct. No. 50-1355.

The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

Respectfully submitted,

Dated: September 25, 2002

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Encls. Exhibits A and B

EXHIBIT A

MARKED VERSION OF CLAIMS SHOWING THE AMENDMENTS

Claims 1, 3, 4, 15, 19 to 22, and 26 have been amended as follows:

1. (Twice amended) An isolated polynucleotide encoding a peptide of a promyostatin polypeptide, said peptide comprising a promyostatin signal peptide domain corresponding to amino acid residues about 1 to 20 of full length promyostatin polypeptide, and said peptide having signal peptide activity, [or a functional peptide portion thereof,] or a polynucleotide complementary [thereto] to said polynucleotide.

3. (Amended) The polynucleotide of claim 2, wherein the vertebrate promyostatin polypeptide is a mammalian promyostatin polypeptide, an avian promyostatin polypeptide, or a piscine promyostatin polypeptide.

4. (Amended) The polynucleotide of claim 1 [3], wherein the [mammalian] promyostatin polypeptide comprises: [is selected from]

a human promyostatin polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:2;

a murine promyostatin polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:4;

a rat promyostatin polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:6;

a chicken promyostatin polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:8;

a baboon promyostatin polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:10;

a bovine promyostatin polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:12;

a porcine promyostatin polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:14; [and]

an ovine promyostatin polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:16.

a turkey promyostatin polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:18; or

a zebrafish promyostatin polypeptide comprising an amino acid sequence as set forth in SEQ ID NO:20.

15. (Amended) The [oligonucleotide] polynucleotide of claim [13] 1, wherein [said polynucleotide encoding] the promyostatin polypeptide is encoded by [or a peptide portion thereof is selected from] SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, SEQ ID NO:11, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, or SEQ ID NO:19 [19, SEQ ID NO:26 and SEQ ID NO:28].

19. (Amended) An isolated polynucleotide encoding a peptide of a promyostatin polypeptide, said peptide comprising a promyostatin [mature] myostatin domain [peptide] corresponding to amino acid residues about 268 to 374 of a full length promyostatin polypeptide, and , said peptide having muscle growth inhibitory activity, or a polynucleotide complementary [thereto] to said polynucleotide.

20. (Amended) The polynucleotide of claim 19, wherein the [myostatin peptide] promyostatin polypeptide is a vertebrate [myostatin peptide] promyostatin polypeptide.

21. (Amended) The polynucleotide of claim 20, wherein the vertebrate [myostatin peptide] promyostatin polypeptide is a mammalian [myostatin peptide] promyostatin polypeptide, an avian promyostatin polypeptide, or a piscine promyostatin polypeptide.

22. (Amended) The polynucleotide of claim 19 [21], wherein the [mammalian] promyostatin myostatin domain [peptide] comprises: [an amino acid sequence selected from]

amino acid residues about 267 to 374 as set forth in SEQ ID NO:2;
amino acid residues about 268 to 375 as set forth in SEQ ID NO:4;
amino acid residues about 268 to 375 as set forth in SEQ ID NO:6;
amino acid residues about 267 to 374 as set forth in SEQ ID NO:8;
amino acid residues about 267 to 374 as set forth in SEQ ID NO:10;
amino acid residues about 267 to 374 as set forth in SEQ ID NO:12;
amino acid residues about 267 to 374 as set forth in SEQ ID NO:14; [and]
amino acid residues about 267 to 374 as set forth in SEQ ID NO:16
amino acid residues about 267 to 374 as set forth in SEQ ID NO:18; or
amino acid residues about 267 to 374 as set forth in SEQ ID NO:20.

26. (Amended) [The] An isolated polynucleotide [of claim 25, wherein the piscine] encoding a promyostatin myostatin domain, or a polynucleotide complementary to said polynucleotide, said myostatin domain having muscle growth inhibitory activity, and said myostatin domain comprising: [peptide comprises an amino acid sequence selected from

amino acid residues about 267 to 374 as set forth in SEQ ID NO:20;]
amino acid residues about 49 to 157 of SEQ ID NO:27; or [and]
amino acid residues about 28 to 136 of SEQ ID NO:29.